India as the potential headquarters of International stem cell research

Stem Cells and Policy was adopted as the focus of the Journal to fill a specific need. The identification of human embryonic stem cells by Jamie Thompson in 1998 ignited an almost unbelievable series of events that at that time and encapsulated the stem cell scientific community in hype propelled to the status of dogma with little if any experimental evidence. This hype resulted from 2 key events. One, the failure of genetic engineering left a void that scientific entrepreneurs rushed to fill. The time was ripe, as the aging population of the United States and other countries sought endlessly for longer, healthy lives. Many of these individuals are and remain very wealthy, and are willing to spend enormous sums of money on any hope of avoidance or cure of disease. Second, the connotations of the meaning of the word "stem cell" was not at all clear, so this cell was elevated to the status of a cell that could restore any lost cell, regenerate any tissue and cure most diseases. This thought seemed to derive directly from the basic qualities of a "stem cell", that quality being that the embryonic stem cell, derived directly from fertilized embryos, indeed generated during gestation all of the component parts of the human organism. This being the case, surely the cell would regenerate parts lost to disease of assault after birth and provide a cure for diseases of aging. These thoughts were not unsupported. Shortly after Dr. Thompson's identification of the human stem cell, Dr. John Gearheart led individuals to believe that these cells could restore intact function of a severed spinal cord. The literature became replete with anecdotal as well as preliminary supportive data showing utility of stem cells in diseases ranging from cardiomyopathy to diabetes. No disease was immune; stem cells could do it all.

Surveying the literature and failed clinical trials, the focus for *Annals of Neurosciences* was developed to provide a different forum, one where dogma developing too rapidly could be challenged;^{1,2} one where reasoned investigations and interpretation would lead to advance, albeit not overnight.

However, in the United States and elsewhere, profit motivated corporations began to sprout and advertised the potential of stem cell therapy to an overly receptive audience, including members of the press. No one was particularly interested in hearing reality; a frenzy developed wherein individuals almost unaminously held dear the promise of stem cell research, and many invested their careers as well as capital in this potential, thought to be assured. When ethical considerations led to deterrence of embryonic stem cell research, investigators actually used this as an excuse for not quickly reaching the goals they promised, and soon developed alternative sources of stem cells which they held out as equivalent cells to attain these goals. Lost in all the hype, fury commotion and fame bestowed upon stem cell researchers was the simple fact that in no case did stem cells restore or regenerate any tissue in adults, nor did they cure any disease. Every advancement was hailed as a remarkable achievement absent the promised attainment of any clinically applicable therapeutic goals.

As investors questioned the attainment of promises, advances were sought with a fury unprecedented in the history of science, Many of these were said to become clinical realities soon, and an eager public kept the field active. We found many studies of stem cells indeed afforded new thoughts and models of development, and highlighted these as we questioned studies that claimed therapeutic success. The latter have not been realized and the reason for this is the haste of investigators to make claims based on flimsy and irreproducible data, claims that were highlighted in high profile journals. Amidst all this fury was one simple fact; the tremendous motive to attain success obscured interpretation of data of key trials and led to a shotgun approach, rather than a well thought out plan to alter conditions and interpret data accurately. Of all the manuscripts we received Stem Cells and Development, the manuscripts received from India presented a striking exception to this rule.

These manuscripts from only a few centers were reliable, not over interpreted and offered new approaches that we thought may lead to success, but not overnight. These facts and others led us to propose India as the center of International stem cell research. This proposal was greeted with surprising enthusiasm by many investigators throughout the world. Recent therapeutic successes in India support our reasoning in this regard and we stand by our hope that this proposal is successfully adopted throughout the world as failures due to rapid and over interpreted experiments still predominate the field. Recent results from India show that a rigorous, scientifically based and carefully interpreted approach will lead to further success.

Economics of Investment

Wealth creation from technology--- one of only a few exportable industries-- involves heavy investment in the form of infrastructure, equipment and reagents. While India has set the standard for economic development as a result of their investment in technology, the cost of accessing electronic resources is very high when initially compared to the revenue initially gained. For example, the cost of patenting and deploying new developments in electronic technology reveals that as few as 5-10 % of patents are eventually commercialized; hence recovering the costs requires capital and it requires manpower and time. With regard to the latter, India in collaboration with US firms very quickly developed an electronic infrastructure which indeed sets the example that serves as a model for development of other technologies. In addition, as outlined by one of us, the costs of research itself grows as it continues,3 this growth being driven by the continuous need to import state of the art facilities and equipment. However, in the end, the investment has paid off in a major way as India's economy outsteps many economies of developed countries. Thus Prime Minister of India recently signed a regulation allowing in-service government scientists to hold equity in companies under their purview. This is recognized as a major paradigm shift in Indian science, and sets the stage for a similar investment in stem cell research. However, the medical institutions are still left clueless as to how to implement this regulation that has seen cabinet approval. A new order of leadership in these Institutions akin to one conceived by famous Valliathan report is urgently required to propel India to lead stem cell translation. Interdisciplinary leadership such as one seen in Department of Biotechnology (DBT), the major funding agency for stem cell research, and National Brain Research Centre (NBRC) could be extended to medical Institutions.

Until recently, India has witnessed a huge cash inflow taking place, funds were not difficult to obtain. Most of these funds are derived from multinational companies investing in knowledge parks and collaborating with Indian Institutes to establishing manufacturing plants in India. These corporations hired many Indian scientists at good salaries. The range of opportunities the stem cell application, if correctly developed, is likely to create will depend on providing health services national and International patients who desire to obtain stem cell therapy but can't obtain it in their own country due to over-regulation. Such profits will stay as long as those governments do not reverse their over-restrictive policies.

Political considerations

Despite India's booming economy, the major expenditure continues to be reserved in India for defence. With rising global violence in the form of terrorism, India is constrained to earmark a big share of its resources in defence and for fighting

terrorism. The Indian government's policy to promote stem cell research despite other national priorities in the manner that ensures safety and efficacy of stem cells is likely to facilitate the unparalleled growth of health industry, results of which are starting to make headlines in the world.

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Denis English, Ph.D Senior Editor

Akshay Anand, Ph.D *Editor in Chief*

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